PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LH/UM 51112	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE 2003/001503	International filing date *(day/month/year)* 26.09.2003	Priority date *(day/month/year)* 01.10.2002
International Patent Classification (IPC) or national classification and IPC A61B 5/06, A61M 5/42 // A61M 5/00		
Applicant Potencia Medical AG et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.03.2004	06.12.2004
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Anna Malmberg /OGU Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE 2003/001503

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished
pages* _____ as amended (together with any statement) under Article 19
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished
pages* _____ received by this Authority on _____
pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing *(specify)*: _____
☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE 2003/001503

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 14-20

because:

☒ the said international application, or the said claims Nos. 15-20
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE 2003/001503

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-4,6,8,13	YES
	Claims	1,5,7,9-12	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

This opinion is based on the claims as originally filed.

Reference is made to the following documents:

D1: US 6305381 B1
D2: WO 9608999 A1

Document D1 discloses an apparatus for detecting an injection port (11) adapted to be subcutaneously implanted in a patient, comprising a magnetic device (22), adapted to emit a local magnetic field, and a magnetic detector (3) adapted to detect the local magnetic field emitted by the magnetic device. The magnetic device or the magnetic detector is designed to be subcutaneously implanted in the patient at the implanted injection port. The magnetic detector or the magnetic device is movable externally along the patient's skin in front of the implanted injection port where the local field emitted by the magnetic device is detected by the magnetic detector, whereby an injection needle can be placed in the established injection position, in order to insert the injection needle through the patient's skin directly into the injection port substantially in the centre thereof. The apparatus also comprises a microprocessor (54), which comprises a sender, capable of sending information about the magnetic detector to outside the patient's body, as the magnetic detector detects the local magnetic field emitted by the magnetic device from outside the patient's body. The direction in which to move the external device may be given by visual and/or audible indication to the user. (See the whole document.)

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V.

Document D2 discloses an apparatus for detecting a magnetic implant with an external sensor. The sensor detects magnetic fields and/or changes of magnetic fields, e.g. from the implant and/or other device cooperating therewith. The magnetic field can be generated for example by means of permanent magnets, induction with in-operated spool and power source in or outside the body etc. The sensor can vary from a simple spool to more advanced elements which are sensitive to magnetic fields, e.g. Hall sensors, magnetic resistive sensors etc.

Statement of reason

What is claimed in claims 1, 5, 7 and 9-12 lacks novelty according to what is known from D1.

It is regarded as obvious details for a person skilled in the art to choose the magnetic device to be a ring-magnet, a permanent magnet, a solenoid or any other suitable kind of magnetic device as for example in D2. In the same way it is regarded as obvious details to choose the detector to be a semiconductor circuit, one or several Hall-elements or any other kind of detector suitable for the purpose, as for example in D2. It is therefore regarded as obvious to a person skilled in the art to, with help from for example D2, choose suitable magnetic devices and detectors to be able to detect the implant properly. Therefore, what is claimed in claims 2-4, 6, 8 and 13 is regarded to lack an inventive step.

Consequently, what is mentioned in claims 1, 5, 7 and 9-12 lacks novelty and is also regarded to lack an inventive step. What is mentioned in claims 2-4, 6, 8 and 13 is new but is regarded to lack an inventive step. The invention according to claims 1-13 is industrially applicable.

PATENT COOPERATION TREATY

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International application No.
PCT/SE 2003/001503

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☒ claims Nos. 14-20

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE 2003/001503

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.../...

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 April 2004 (15.04.2004)

PCT

(10) International Publication Number
WO 2004/030536 A1

(51) International Patent Classification[7]: A61B 5/06, A61M 5/42 // 5/00

(21) International Application Number: PCT/SE2003/001503

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(30) Priority Data:
10/260,546 1 October 2002 (01.10.2002) US

(71) Applicant *(for all designated States except US)*: POTENCIA MEDICAL AG [CH/CH]; Zugerstrasse 74, CH-6341 Baar (CH).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: FORSELL, Peter [SE/CH]; Aegeristrasse 66, CH-6300 Zug (CH).

(74) Agent: HAGSTRÖM, Leif; Bergenstråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE).

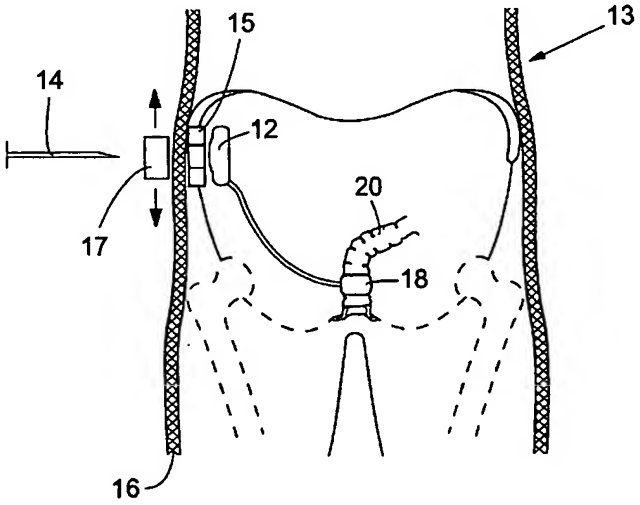
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DETECTION OF IMPLANTED INJECTION PORT



(57) Abstract: An apparatus for detecting an injection port (12) subcutaneously implanted in a patient (13) comprises a magnetic device (15), such as a permanent magnet or a solenoid, that emits a local magnetic field, and a magnetic detector (17), preferably including at least one Hall element, that detects the local magnetic field. The magnetic device (15) is designed to be subcutaneously implanted in the patient at the implanted injection port (12), and the magnetic detector (17) is movable externally along the patient's body to establish an injection position at the patient's skin (16) in front of the implanted injection port where the local magnetic field emitted by the magnetic device is detected by the magnetic detector. As a result, an injection needle (14) can be placed in the established injection position, in order to insert the injection needle through the patient's skin (16) directly into the injection port substantially in the centre thereof.

WO 2004/030536 A1

DETECTION OF IMPLANTED INJECTION PORT

The present invention relates to an apparatus and a method for detecting an injection port subcutaneously implanted in a patient.

It is important to locate the position of an injection port connected to a hydraulically operable surgical implant in a patient to be able to accurately inject a needle of a syringe through the membrane of the injection port (or simply for the purpose of locating the exact position of the injection port, or alternatively locating the membrane of the injection port), for supplying hydraulic fluid to or withdrawing hydraulic fluid from the implant. Such an injection port is typically arranged in connection (via a conduit) to a hydraulically adjustable implant, for example a food intake restriction device, implanted inside an obese patient.

Currently, a nurse or doctor locates an implanted injection port by simply feeling with the fingers on the patient's skin to find out where the injection port is situated. However, the nurse or doctor cannot know exactly where the injection needle should penetrate the skin, in order to penetrate the centre of the membrane of the injection port.

The object of the present invention is to provide an inexpensive apparatus and methods for accurately detecting an injection port subcutaneously implanted in a patient to enable an injection needle to safely penetrate the patient's skin directly into the centre of the injection port.

This object is obtained by an apparatus of the kind stated initially, comprising a magnetic device adapted to emit a local magnetic field, and a magnetic detector adapted to detect the local magnetic field emitted by the magnetic device. The magnetic device is designed to be subcutaneously implanted in the patient at the implanted injection port, and

the magnetic detector is movable externally along the patient's body to establish an injection position at the patient's skin in front of the implanted injection port where the local magnetic field emitted by the magnetic device is detected by the magnetic detector. Alternatively, the magnetic detector is designed to be subcutaneously implanted and the magnetic device is movable along the patient's body to establish the injection position at the patient's skin in front of the implanted injection port where the local magnetic field emitted by the magnetic device is detected by the magnetic detector.

Thus, the accurate injection position on the patient's skin in front of the injection port, which is hidden behind the skin, can be established using the apparatus of the present invention. With an injection needle placed in this injection position, it is an easy task to properly and safely insert the injection needle through the patient's skin directly into the injection port substantially in the centre thereof. The present invention is particularly advantageous to practise in obese people where an implanted injection port can be difficult to manually locate.

Generally, the magnetic detector includes a semiconductor circuit, preferably in the form of at least one Hall-element. By using one or more Hall-elements, a special type of semiconductor known in the art, it is easy to locate the centre of the magnetic field emitted by the magnetic device. The magnetic detector suitably comprises several Hall-elements grouped around a central point in a triangular or square configuration. For example, three Hall-elements may be arranged at the corners of an equilateral triangle. An important advantage is that the Hall-elements are able to detect even a weak magnetic field emitted from the magnetic device.

In accordance with a main first embodiment of the invention, the magnetic device is designed to be subcutaneously implanted in the patient at the implanted injection port to emit the local magnetic field through a portion of the patient's skin adjacent to the injection port, and the magnetic detector is movable externally along the patient's body to establish the injection position where the local magnetic field is detected by the magnetic detector. In this embodiment, the magnetic device may include a ring-magnet to be positioned around the membrane of the injection port, so that an injection needle can be inserted through the ring-magnet and the membrane of the injection port. The magnetic detector may be adapted to emit a sound when detecting the local magnetic field. Alternatively, the movable magnetic detector may be provided with at least one diode adapted to emit light when the detector detects the local magnetic field, or be provided with a display adapted to indicate when the detector detects the local magnetic field.

In accordance with a second embodiment of the invention, the magnetic detector is designed to be subcutaneously implanted in the patient at the implanted injection port, and the magnetic device is adapted to emit the local magnetic field through the patient's skin from outside the patient's body and is movable externally along the patient's body to establish the injection position where the local magnetic field is detected by the implanted magnetic detector. The movable magnetic device is suitably adapted to establish the injection position in front of the subcutaneously implanted injection port. In its simplest form, the implanted magnetic detector may be adapted to emit a sound when detecting the local magnetic field. In a more sophisticated form, a sender may be implantable in the patient's body and be capable of sending information about the magnetic detector to outside the patient's body, as the implanted magnetic detector detects the

local magnetic field emitted by the movable magnetic device from outside the patient's body. For example, the implanted sender may send RF signals that inform when the implanted detector detects the local magnetic field, whereby an accurate injection position at the patient's skin can be established. The accurate injection position may be directly or indirectly correlated to the intensity of magnetism detected by the magnetic detector.

The magnetic device may be a solenoid or a permanent magnet, which is sending out a magnetic field.

The present invention also relates to a method of detecting a wireless injection port subcutaneously implanted in a patient. The method comprises providing a magnetic device capable of emitting a local magnetic field through the patient's skin, providing a magnetic detector adapted to detect the local magnetic field emitted by the magnetic device, subcutaneously implanting the magnetic device or magnetic detector in the patient at the implanted injection port, moving the magnetic detector or magnetic device externally along the patient's body, and establishing an injection position at the patient's skin where the local magnetic field emitted by the magnetic device is detected by the magnetic detector. Then, an injection needle can be placed in the injection position where the local magnetic field has been detected to accurately insert the needle through the patient's skin directly into the injection port.

In accordance with a first alternative of the method of the invention, the magnetic device is subcutaneously implanted, the magnetic detector is moved externally along the patient's body, and the injection position is established at the patient's skin where the local magnetic field emitted by the implanted magnetic device is detected by the moving magnetic detector.

In accordance with a second alternative of the method of the invention, the magnetic detector is subcutaneously implanted, the magnetic device is moved externally along the patient's body, and the injection position is established at the patient's skin where the local magnetic field emitted by the moving magnetic device is detected by the implanted magnetic detector. When practising the second alternative method it may further comprise implanting a sender and using the sender to send information to outside the patient's body confirming when the implanted magnetic detector detects the local magnetic field emitted by the moving magnetic device.

When practising the above detection method a semiconductor circuit, preferably comprising at least one Hall-element, may be used as the magnetic detector.

The present invention also provides a surgical method for treating a patient having a disease comprising the steps of: insufflating the patient's abdomen with gas; implanting a hydraulically operable implant designed for treating reflux disease, urinary incontinence, impotence, anal incontinence or obesity in the abdomen by using surgical instruments through the trocars; subcutaneously implanting an injection port for supplying hydraulic fluid for the operation of the implant and a magnetic device at the injection port for emitting a local magnetic field through the injection port and the adjacent skin portion of the patient; post-operatively moving an external magnetic detector along the patient's body to a position in which the local magnetic field emitted by the implanted magnetic device is detected by the magnetic detector; bringing an injection needle to the position in which the local magnetic field is detected; and moving the injection needle to penetrate the patient's skin into the injection port for supplying hydraulic fluid to or withdrawing hydraulic fluid from the injection port.

Alternatively, the surgical method may comprise subcutaneously implanting a magnetic detector at the injection port and post-operatively moving an exterior magnetic device emitting a local magnetic field along the patient's body to a position in which the local magnetic field emitted by the exterior magnetic device is detected by the implanted magnetic detector.

The invention is described in more detail in the following with reference to the accompanying drawings, in which

Figure 1 shows a connection diagram for a magnetic detector of the apparatus according to the present invention,

Figure 2 schematically illustrates in a diagram the output of the magnetic detector positioned in front of a magnetic device of the apparatus of the invention.

Figure 3 is a schematic view of an embodiment where the magnetic device is subcutaneously implanted in a patient, and the magnetic detector is movable externally along the patient's body,

Figure 4 is a schematic view of an embodiment where the magnetic detector is subcutaneously implanted in the patient and the magnetic device is movable externally along the patient's body,

Figure 5 is a schematic view of a hydraulically adjustable constriction device designed for treating reflux disease, urine incontinence, anal incontinence or obesity, and

Figure 6 illustrates an embodiment according to the present invention using Hall-elements as the magnetic detecting device.

Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

Figure 1 shows a connection circuit 1 for a magnetic detector 2 of the apparatus according to the present

invention. A magnetic device in the form of a ring-magnet 3, which can be a solenoid or a permanent magnet, is implanted in a patient's body. Located outside the body and positioned in front of the implanted ring-magnet 3 is magnetic detector 2, which includes three linear magnetic field sensors 4 grouped in a triangular configuration. Each sensor 4 includes a semiconductor circuit such as a Hall-element or the like. Sensors 4 are connected to signal-conditioning amplifiers 5, which in turn, are connected to an A/D-converter 6. A microprocessor 7 is connected to A/D-converter 6. To visually display the output signals of sensors 4, a display-device 8 is connected to microprocessor 7.

The graph shown in Fig. 2 illustrates, in principle, how the information obtained by detector 2 can be presented. On the X-axis in the graph is the position of detector 2 relative to the magnetic device. On the Y-axis is the combined output of sensors 4 of detector 2. Thus, the graph of Fig. 2 shows the position "X" of detector 2 relative to the magnetic device as a function of detector 2's output "Y". To illustrate this method of detecting, a magnetic device in the form of a ring-magnet 9 is shown relative to the graph of Figure 2. Ring-magnet 9 is shown in cross-section to show the positions of its magnetic north pole N and south pole S, respectively. Fig. 2 depicts the case where magnetic detector 2 (not shown in Fig. 2) has been centred in front of ring-magnet 9 and where all of the sensors 4 produce a maximum output, which is shown as peaks 10,11 in the graph of Fig. 2. Sensors 4 are connected (*e.g.*, by connection circuit 1 shown in Fig. 1) to display device 8, which may display the graph shown in Fig. 2, or alternatively, a numeral result from the measurements taken by sensors 4.

Fig. 3 shows an embodiment of the apparatus of the present invention for detecting an injection port 12 subcutaneously implanted in a patient 13 suffering from anal

incontinence to enable positioning of an injection needle 14 outside the patient's body for safe and accurate injection in the injection port 12. Injection port 12 is hydraulically connected to a hydraulically adjustable artificial sphincter 18 applied to the patient's rectum 20. The apparatus also includes a magnetic device in the form of a ring-magnet 15 subcutaneously implanted in the patient 13 around injection port 12. Magnetic device 15 emits a local magnetic field extending through a portion of the patient's 13 skin 16 adjacent to injection port 12. The apparatus further includes an external, separate magnetic detector 17 that may be manually moved along the patient 13's body to establish an injection position at the patient's skin where the local magnetic field emitted by magnetic device 15 is detected by magnetic detector 17. When this injection position has been established, injection needle 14 can be located in the same position to accurately insert the needle 14 through patient's skin directly into injection port 12.

Fig. 4 shows an embodiment of the invention identical to the embodiment according to Fig. 3, except that a magnetic detector 21 is subcutaneously implanted in patient 13 at injection port 12 and an external separate magnetic device in the form of a ring-magnet 22 that emits a local magnetic field through patient's 13 skin 16 is provided. Ring-magnet 22 may be manually moved externally along the patient's 13 body to establish an injection position at the patient's skin where the local magnetic field emitted by magnetic device 22 is detected by the implanted magnetic detector 21. A sender 23 is implanted in patient 13 and sends information about the status of magnetic detector 21. Thus, when magnetic detector 21 detects the local magnetic field emitted by external ring-magnet 22, sender 23 sends information confirming that magnetic device 22 is in the proper injection position for accurate positioning of the injection needle 14 outside the

patient's body. When this injection position has been established, the injection needle14 can be placed in the same position to accurately insert the needle through patient's skin directly into injection port 12.

Fig. 5 shows an example of the artificial sphincter 18 shown in Figs. 3 and 4. Sphincter 18 includes a hydraulically adjustable constriction device 24 to be applied around the patient's rectum (not shown in Fig. 5). Constriction device 24 has a cavity 25 which can be inflated by supplying hydraulic fluid thereto, via implanted injection port 12, to close the rectum, and be deflated by withdrawing hydraulic fluid therefrom, to open the rectum. This type of constriction device may also be used as an artificial sphincter for treating patient's suffering from heartburn and reflux disease or urinary incontinence, when combined with the apparatus of the present invention. Furthermore, constriction device 24 may be used for forming an adjustable stoma opening in the stomach or esophagus of an obese patient to treat obesity or for restricting the penile exit blood flow to treat an impotent patient, when combined with the apparatus of the invention.

Fig. 6 shows an advantageous design of the embodiment shown in Fig. 3, in which the external magnetic detector 17 includes three symmetrically arranged Hall-elements 27 which are grouped around a central point in a triangular configuration. The magnetic device is implanted and includes a ring-magnet 28 surrounding the centre 29 of the implanted injection port 12. When magnetic detector 17 is moved to a position in which Hall-elements 27 are placed symmetrically above and around ring-magnet 28, as illustrated in Fig. 6, magnetic detector 17 detects a maximum intensity of the magnetic field emitted by the implanted magnet 28, whereby the most accurate position where the injection needle 14 should be inserted into injection port 12 is established. As an

alternative, the design described above may be practised in the embodiment shown in Fig. 4. Thus, the implanted magnetic detector 21 may include the three Hall-elements 27 and the external magnetic device 22 may include the ring-magnet 28.

Although the present invention has been described in terms of a particular embodiment and process, it is not intended that the invention be limited to that embodiment. Modifications of the embodiment and process within the spirit of the invention will be apparent to those skilled in the art. The scope of the invention is defined by the claims that follow.

CLAIMS

1. An apparatus for detecting an injection port (12) adapted to be subcutaneously implanted in a patient (13), comprising:

a magnetic device (15;22) adapted to emit a local magnetic field, and

a magnetic detector (17;21) adapted to detect the local magnetic field emitted by the magnetic device,

wherein the magnetic device (15) or magnetic detector (21) is designed to be subcutaneously implanted in the patient at the implanted injection port (12), and the magnetic detector (17) or magnetic device (22) is movable externally along the patient's body to establish an injection position at the patient's skin (16) in front of the implanted injection port where the local magnetic field emitted by the magnetic device is detected by the magnetic detector, whereby an injection needle can be placed in the established injection position, in order to insert the injection needle through the patient's skin directly into the injection port substantially in the centre thereof.

2. An apparatus according to claim 1, wherein the magnetic detector (17;21) comprises a semiconductor circuit.

3. An apparatus according to claim 2, wherein the semiconductor circuit of the magnetic detector (17;21) comprises at least one Hall-element (27).

4. An apparatus according to claim 3, wherein the magnetic detector (17;21) comprises several Hall-elements (27) grouped around a central point in a triangular or square-configuration.

5. An apparatus according to any one of claims 1-4, wherein the magnetic device (15) is designed to be subcutaneously implanted in the patient at the implanted injection port (12) to emit the local magnetic field through a portion of the patient's skin (16) adjacent to the injection port, and the magnetic detector (17) is movable externally along the patient's body to establish the injection position where the local magnetic field is detected by the magnetic detector.

6. An apparatus according to claim 5, wherein the magnetic device comprises a ring-magnet (15) designed to be implanted around the membrane of the implanted injection port (12).

7. An apparatus according to any one of claims 1-4, wherein the magnetic detector (21) is designed to be subcutaneously implanted in the patient at the implanted injection port (12), and the magnetic device (22) is adapted to emit the local magnetic field through the patient's skin (16) from outside the patient's body and is movable externally along the patient's body to establish the injection position where the local magnetic field is detected by the implanted magnetic detector.

8. An apparatus according to claim 7, wherein the magnetic device comprises a ring-magnet (22).

9. An apparatus according to claim 7 or 8, further comprising a sender (23) implantable in the patient's body and capable of sending information about the magnetic detector (21) to outside the patient's body, as the magnetic detector detects the local magnetic field emitted by the magnetic device (22) from outside the patient's body.

10. An apparatus according to any one of claims 1-9, wherein the magnetic detector is adapted to emit a sound when detecting the local magnetic field.

11. An apparatus according to any one of claims 2-6, wherein the magnetic detector is provided with at least one diode adapted to emit light when the detector detects the local magnetic field.

12. An apparatus according to any one of claims 2-6, wherein the magnetic detector is provided with a display adapted to indicate when the detector detects the local magnetic field.

13. An apparatus according to any one of claims 1-12, wherein the magnetic device (15;22) is a solenoid or a permanent magnet.

14. Use of the apparatus according to any one of claims 1-13 for detecting a subcutaneously implanted injection port, which is hydraulically connected to an implanted hydraulically adjustable constriction device for treating reflux disease, obesity, anal or urinary incontinence, or impotence.

15. A method of detecting an injection port (12) subcutaneously implanted in a patient, comprising:

providing a magnetic device (15;22) capable of emitting a local magnetic field through the patient's skin (16),

providing a magnetic detector (17;21) adapted to detect the local magnetic field emitted by the magnetic device,

subcutaneously implanting the magnetic device (15) or magnetic detector (21) in the patient at the implanted injection port (12),

moving the magnetic detector (17) or magnetic device (22) externally along the patient's body, and

establishing an injection position at the patient's skin (16) in front of the implanted injection port where the local magnetic field emitted by the magnetic device is detected by the magnetic detector.

16. A method according to claim 15, wherein the magnetic device (15) is subcutaneously implanted, the magnetic detector (17) is moved externally along the patient's body, and the injection position is established at the patient's skin (16) where the local magnetic field emitted by the implanted magnetic device is detected by the moving magnetic detector.

17. A method according to claim 15, wherein the magnetic detector (21) is subcutaneously implanted, the magnetic device (22) is moved externally along the patient's body, and the injection position is established at the patient's skin (16) where the local magnetic field emitted by the moving magnetic device is detected by the implanted magnetic detector.

18. A method according to claim 17, further comprising implanting a sender (23) and using the sender to send information to outside the patient's body confirming when the implanted magnetic detector (21) detects the local magnetic field emitted by the exterior magnetic device (22).

19. A method according to any one of claims 15-18, wherein a semiconductor circuit is used as the magnetic detector (17;21).

20. A method according to claim 19, wherein the semiconductor circuit comprises at least one Hall-element.

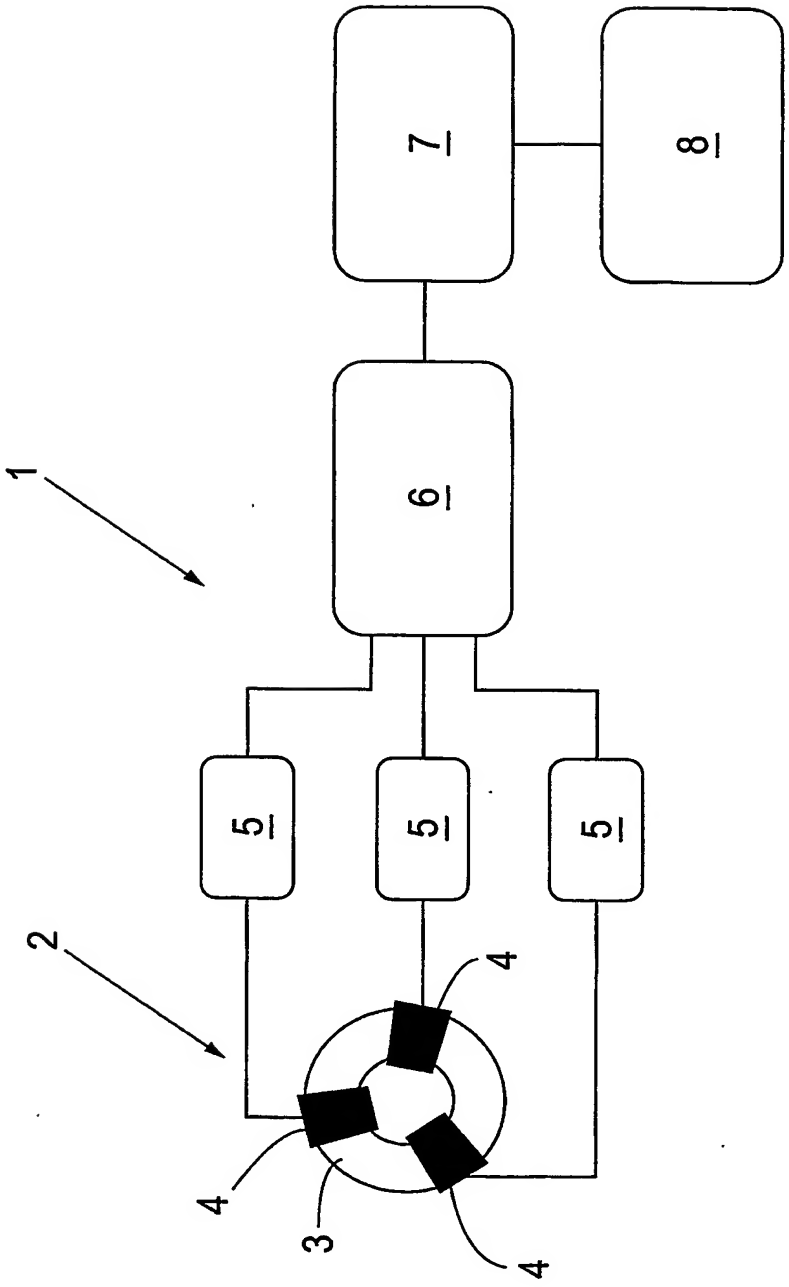


Fig. 1

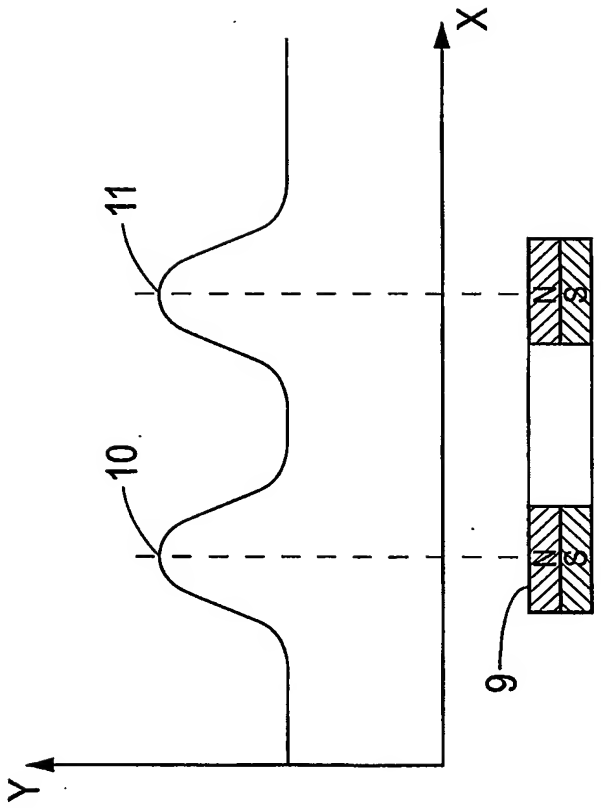


Fig. 2

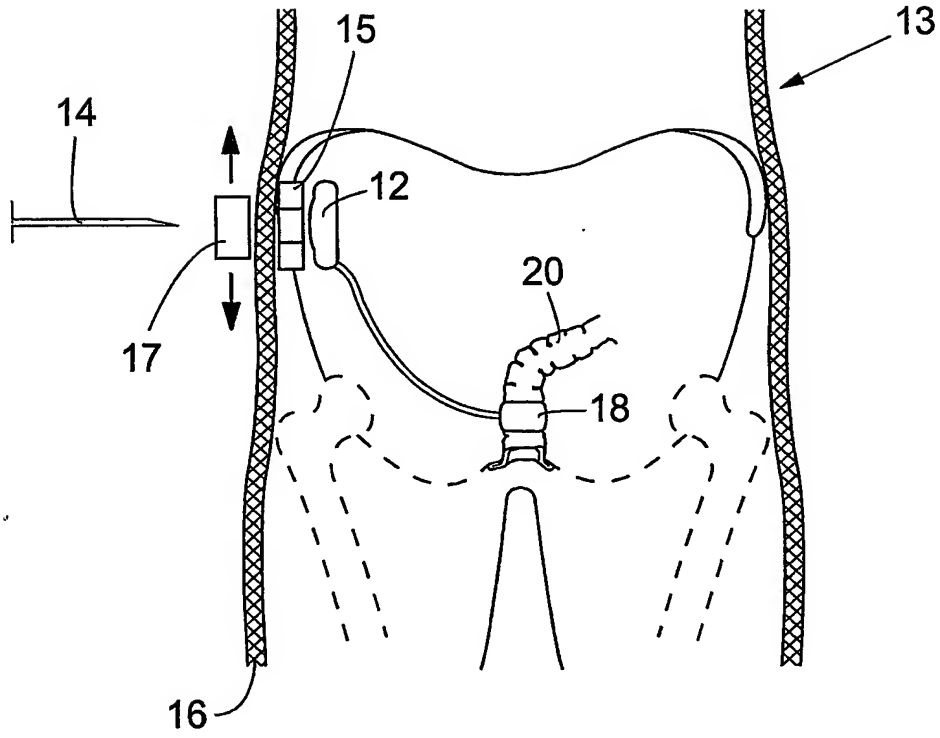


Fig. 3

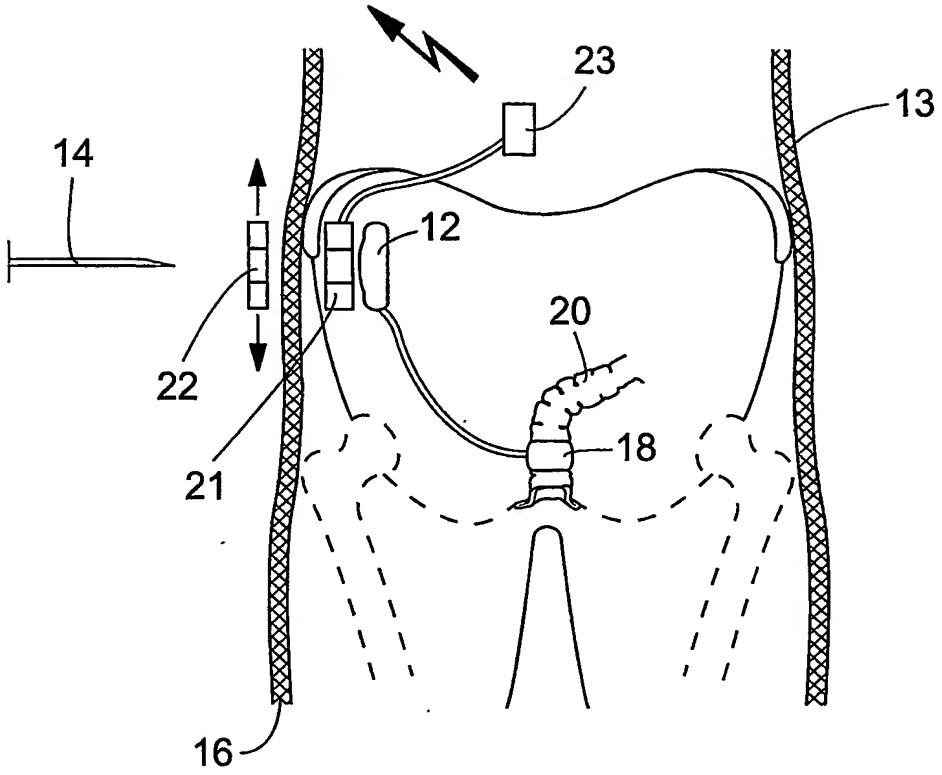


Fig. 4

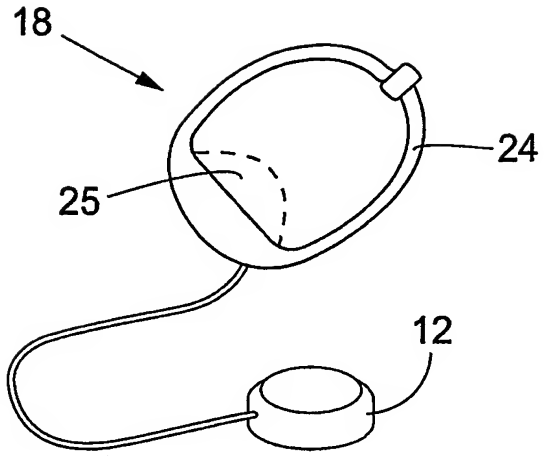


Fig. 5

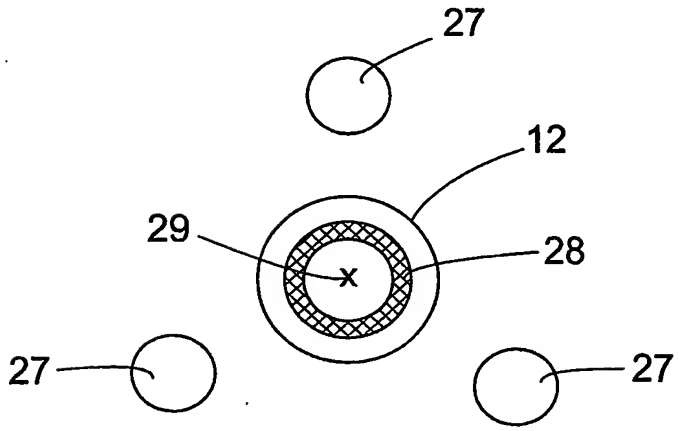


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/01503

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/06, A61M 5/42 // A61M 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6305381 B1 (WEIJAND, K.J. ET AL), 23 October 2001 (23.10.01), see the whole document	1-13,15-20
A	WO 9608999 A1 (LENNERNÄS, B.), 28 March 1996 (28.03.96), page 3, line 5 - page 4, line 35, figures 1-2, abstract	2-4,6,8,13, 19-20
A	US 5622169 A (GOLDEN, R.N. ET AL), 22 April 1997 (22.04.97), abstract	2-4,6,8,13, 19-20
A	WO 9632060 A1 (NAVION BIOMEDICAL CORPORATION), 17 October 1996 (17.10.96), see the whole document	1-13,15-20

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 December 2003	08-01-2004
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Anna Malmberg /OGU Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 03/01503

Box I **Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14 - 20
because they relate to subject matter not required to be searched by this Authority, namely:

see extra sheet

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II **Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Claim 14 relates to the use of an apparatus for detecting a subcutaneously implanted injection port. The purpose of what is claimed is to detect an injection port which is a step of a therapeutic method to treat a disease such as urinary incontinence, unless anything else is mentioned. Thus the claim 14 implicitly reveals a therapeutic method, for which the International Search Authority is not required to carry out an international search (Rule 39.1(iv)). Consequently no search has been conducted for claim 14.

The method in claims 15-20 comprises a step of implanting a magnetic device subcutaneously in a patient. As the method includes the step of surgery on a patient, this necessarily requires medically skilled staff and the method is to be carried out under the responsibility of a doctor. Thus, the International Search Authority is not required to carry out an international search for these claims (Rule 39.1(iv)). Nevertheless a search was conducted with these claims in mind but with the focus on the physical device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

31/10/03

International application No.
PCT/SE 03/01503

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6305381 B1	23/10/01	DE 10003338 A	30/11/00
		FR 2788983 A,B	04/08/00
		AU 2654499 A	16/08/99
		EP 1052935 A	22/11/00
		US 6009878 A	04/01/00
		WO 9938438 A	05/08/99
WO 9608999 A1	28/03/96	EP 0955879 A	17/11/99
		JP 10505776 T	09/06/98
		SE 9403193 A	23/03/96
US 5622169 A	22/04/97	AU 689136 B	26/03/98
		AU 716011 B	17/02/00
		AU 5269898 A	19/03/98
		AU 7835694 A	03/04/95
		CA 2171717 A	23/03/95
		DE 69421820 D,T	16/03/00
		DK 719420 T	01/05/00
		EP 0719420 A,B	03/07/96
		SE 0719420 T3	
		ES 2141257 T	16/03/00
		JP 9503054 T	25/03/97
		US 5425382 A	20/06/95
		US 5902238 A	11/05/99
		WO 9508130 A	23/03/95
WO 9632060 A1	17/10/96	AU 714148 B	23/12/99
		AU 5480096 A	30/10/96
		CA 2218093 A	17/10/96
		EP 0822778 A	11/02/98
		JP 11503630 T	30/03/99
		US 5645065 A	08/07/97